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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,719	03/23/2004	Kenneth P. Hoyme	279.721US1	2654

21186 7590 11/03/2005

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT PAPER NUMBER

3762

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,719

Applicant(s)

HOYME ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25, 27-30, 32, 51, 52 and 54-56 is/are rejected.
- 7) ☒ Claim(s) 26, 31 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10172005.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-23 in the reply filed on 10/17/2005 is acknowledged. With the inclusion of linking claim 51, claims 1 and 24 are not deemed independent or distinct. Therefore, the restriction is withdrawn and all pending claims (1-32 and 51-56) will be considered. Examiner acknowledges the cancellation of claims 33-50.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/17/2005 is noted. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In regards to claim 1, "the electrical input" is lacking antecedent basis.

6. In regards to claims 4 and 8, "other memory cells" is inferentially included, rendering unclear whether this element is part of the claimed invention. It is suggested to first positively recite the element before further limiting it.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3, 6, 7, 10-14, 16-22, 24, 25, 27-30, 32, 51, 52, and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh (6,532,389) in view of Foster et al. (2003/0036776). Shahandeh discloses a cardiac rhythm management system that detects and corrects single bit and multiple bit errors (abstract) in the memory of a medical device that have been caused by radiation (col. 1, line 61).

Art Unit: 3762

Please note that the examiner is alternatively interpreting the fact that single bit errors are detected and corrected for every read cycle as showing that multiple single bit errors, or multiple bit errors, are detected and corrected. Additionally, Shahandeh's system comprises a telemetry circuit (100), an external programmer (102), an output (44), a therapy circuit coupled to the output (70), a sensing input (42 and 82), and a cardioverter defibrillator (116). Finally, Shahandeh's invention executes memory scrubbing at a lower priority than therapy and withholds therapy while in memory scrubbing mode (memory scrubbing is done between therapies) (col. 14, line 22).

Please note that the examiner is interpreting "increasing the rate of detecting and correcting single bit errors" as being an inherent property of Shahandeh's invention. Since this invention "scrubs" the memory for each write function, an increase in high-energy radiation will inherently increase the errors that will be detected and corrected because there will be more errors and all errors are detected and corrected.

10. Shahandeh does not disclose initiating, exiting, or altering the mode when the device is in the presence of high energy radiation by detecting a rate of memory errors compared to a threshold; a sensor; a timer to end the mode; enabling and disabling the mode from an external device; an external device that is an RF transmitter associated with a radiation source; or a radiation detector circuit.

11. Foster et al. teach of an implantable cardiac rhythm management device that switches modes when a high radiation environment is detected (par. 0032) to protect the most sensitive portions of the device, by determining a rate of internal errors (par. 0037 and 0045) to accurately activate the mode change when exposed to high-energy

radiation. Foster et al. also teach of utilizing a sensor (par. 0041) to determine that the device is in a high-energy radiation environment, deactivating the mode when the device is no longer in the high-energy radiation environment (par. 0047) to allow the utilization of the more desirable mode when not in a high-energy radiation environment based on a threshold rate (one per time period) and time duration (par. 0045), enabling and disabling the mode with an external RF transmitter associated with a radiation source (par. 0053) to allow an MRI device to directly activate the mode change, and a radiation detector circuit (par. 0041) to provide a means to switch modes in cases where radiation is higher than background radiation.

12. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Shahandeh's invention by switching modes when a high radiation environment is detected to protect the most sensitive portions of the device, determining a rate of internal errors to accurately activate the mode change when exposed to high-energy radiation, utilizing a sensor to determine that the device is in a high-energy radiation environment, deactivating the mode when the device is no longer in the high-energy radiation environment to allow the utilization of the more desirable mode when not in a high-energy radiation environment based on a threshold rate and time duration, enabling and disabling the mode with an external RF transmitter associated with a radiation source to allow an MRI device to directly activate the mode change, and a radiation detector circuit to provide a means to switch modes in cases where radiation is higher than background radiation.

Art Unit: 3762

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh in view of Foster et al. as applied to claim 13 above, and further in view of Linberg (2002/0032470). The modified invention of Shahandeh includes the essential features of the claimed invention except for programmer connectivity to a global computer network. Linberg teaches of an implantable cardiac rhythm management device whose programmer communicates with a web-based data center to import expertise to the patient environment (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the modified invention of Shahandeh with a programmer with connectivity to a global computer network to allow a remote medical expert to diagnose problems, monitor the patient, or provide software enhancements to the implanted device.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shahandeh in view of Foster et al. as applied to claim 19 above, and further in view of Ullestad et al. (6,635,048). The modified invention of Shahandeh includes the essential features of the claimed invention except for providing drug therapy to the patient. Ullstad et al. teaches of providing a drug delivery device with a back-up memory to provide a reliable device to treat a variety of diseases that require controlled release drugs. Therefore, it would have been obvious to provide the modified invention of Shahandeh with a drug delivery device to provide a reliable means to treat a variety of diseases that require controlled release drugs.

Allowable Subject Matter

15. Claims 26, 31, and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Claims 4, 5, 8, and 9 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

17. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or anticipate providing a "memory scrubbing mode" based on the effect of radiation on certain memory cells that are more sensitive than others.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK



JEFFREY R. JASTRZAB
PRIMARY EXAMINER
11/1/05